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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,583	03/18/2004	Edgardo Costa Maiani	DID1046US	7264
9561 7590 04/29/2009 POPOVICH, WILES & O'CONNELL, PA 650 THIRD AVENUE SOUTH SUITE 600 MINNEAPOLIS, MN 55402			EXAMINER CHAPMAN, GINGER T	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 04/29/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,583

Applicant(s)

MAIANTI ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the claims

1. Claims 1-3 And 7 are pending in the application, claim 1 is amended.

Drawings

2. The drawings were received on January 6, 2009. These drawings are acceptable.
3. **Withdrawn Objections:**
4. The objection to the drawings for not including reference characters, made of record in the previous Office action, is withdrawn in view of Applicants' amendment to the drawings.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gremel et al (US 6,302,860 B1) in view of Ito et al (US 5,147,187) and further in view of De Wall (US 3,256,883).

8. With respect to claim 1, as best depicted in Figures 3 and 4, Gremel discloses an integrated device for oxygenating and filtering blood flowing through an extracorporeal blood circuit comprising: a bubble trap 30 having an inlet 44 for receiving venous blood and an outlet 48 for supplying venous blood; a blood pump 26 having an inlet connected to receive venous blood and an outlet; an oxygenator 28 having an inlet connected to receive venous blood and an outlet for supplying oxygenated blood; an arterial blood filter 30 having an inlet connected to receive blood and an outlet for supplying filtered blood; and a monolithic housing (fig. 4) including a first portion for defining the bubble trap (c. 2, ll. 61-63), wherein the device does not comprise a venous reservoir (c. 2, ll. 26-31; abstract).

9. Gremel discloses the claimed invention but is silent on the location of the outlet positioned on the blood pump. As best depicted in Figures 13 and 14, Ito teaches a pump 30 embodiment wherein the outlet 30b is positioned at a top of the blood pump. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the outlet of the pump of Gremel at a top of the pump as taught by Ito since Ito states, at c. 13, ll. 33-35, that the benefit of arranging the pump with this design is that locating the outlet in this position allows blood entering the inflow inlet to be pumped toward and discharged outwardly from the outlet, and it has been held that rearranging parts of an invention involves only routine skill in the art.

10. Gremel discloses the claimed invention except for a heat exchanger. De Wall, at c. 1, ll. 30-33, provides motivation a heat exchanger in an integrated device for oxygenating and filtering blood. As best depicted in Figures 1 and 2, De Wall teaches a heat exchanger 52 (c. 4, ll. 28-39). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Gremel to include a heat exchanger as taught by De Wall since De Wall states, at c. 5, ll. 3-6, that the benefit of a heat exchanger is that it allows for effective temperature control of the blood.

11. With respect to claim 7, Gremel discloses the housing is configured such that blood flowing through the circuit is directed through the bubble trap before the blood enters the blood pump (fig. 3; c. 2, ll. 26-31; ll. 58-63).

12. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gremel in view of Ito in view of De Wall and further in view of Israelev (US 5,924,848).

13. With regard to claims 2 and 3, Gremel in view of DeWall disclose the claimed invention except for the blood pump comprises a centrifugal pump positioned such that the axis of the pump is horizontal. Israelev teaches a centrifugal pump for extracorporeal blood circuit in which the axis of the pump may be horizontal or vertical (c. 3, ll. 58-59). When the axis of pump rotation is horizontal, it appears that the outlet would perform as though the outlet is on the top, when the axis is vertical, the outlet would perform as though it were tangential. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the pump of Israelev in the circuit of Gremel since Israelev states, at c. 3, ll. 54-60 that the benefit of using such a pump is that it is stable when the direction of the pump's axis

of rotation is changed because the position of the housing is changed to allow for flexibility in positioning the pump.

Response to Arguments

14. Applicant's arguments with respect to claims 1-3 and 7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

16. Clausen et al (US 4,984,972) Figure 1 discloses a centrifugal blood pump having an outlet 20 positioned at a top of the pump.

17. Rafferty et al (US 3,970,408) teaches a centrifugal blood pump having outlets positioned at tops of the pumps (Fig. 1 (36); Fig. 9 (209, 215)).

18. Wampler et al (US 5,695,471) discloses centrifugal blood pump having outlet 16 positioned at the top.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
04/16/09
/Tatyana Zalukaeva/

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Supervisory Patent Examiner, Art Unit 3761